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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

May 27, 2003

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-20

Dan G. Ward, Co-owner
Ward Dairy
227 East 400 South
Burley, Idaho 83318

WARNING LETTER

Dear Mr. Ward:

An investigation at your dairy located at 227 East 400 South, Twin Falls, Burley, Idaho, by our investigators on April 16 and 17, 2003, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). The investigation also revealed that you administer drugs to cattle in violation of Section 501(a)(5) of the Act.

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act.

- On or about December 27, 2002, you sold a dairy cow identified with Ear Tag #744 and listed as USDA Case # 01-1245-ID, Form # 433483, for slaughter as human food to [REDACTED].
[REDACTED] USDA analysis of tissue samples collected from that animal identified the presence of Penicillin in the kidney tissue at 0.70 parts per million (ppm), 0.51 ppm in the liver tissue, and 0.07 ppm in the muscle tissue. A tolerance of 0.05 ppm has been established for residues of Penicillin in the uncooked edible tissues of cattle. See Title 21, Code of Federal Regulations (C.F.R.), Section 556.510.

- On or about July 10, 2002, you sold a dairy cow identified with Ear Tag # 1163 and listed as USDA Case # 01-1245-ID, Form #433451, for slaughter as human food to [REDACTED]. USDA analysis of tissue samples collected from that animal identified the presence of Sulfadimethoxine in the liver tissue at 0.60 ppm and 0.35 ppm in the muscle tissue. A tolerance of 0.1 ppm has been established for residues of Sulfadimethoxine in edible tissues of cattle. See 21 C.F.R. § 556.640.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." Insanitary conditions exist at your dairy because you hold and process animals under conditions that are inadequate to assure that medicated animals containing excessive and possibly harmful drug residues do not enter the food supply.

Additionally, failure to use a drug in conformance with its approved labeling renders it unsafe within the meaning of Section 512(a)(1) of the Act and, therefore, adulterated within the meaning of Section 501(a)(5) of the Act. The presence of excessive levels of Penicillin and Sulfadimethoxine residues in cattle that you offered for sale, establish that these drugs were not used in conformance with their approved labeling.

For example, our investigator noted the following conditions on your farm:

1. You failed to follow label directions for a medication you administered to your animal and you administered a product in excess of the recommended dosages in violation of 21 C.F.R. §§ 530.11(a), (c) and (d).
2. You failed to follow appropriate withdrawal procedures that would assure animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
3. You failed to maintain treatment/medication records which identify (a) the dosage administered and (b) the drugs' pre-slaughter withdrawal time.
4. You failed to maintain a system to review treatment records prior to offering animals for slaughter for human food, to assure that drugs used have had the appropriate withdrawal times have been observed.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures to prevent future violations. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Michael J. Donovan, Compliance Officer at (425) 483-4906.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc: Dr. Ahmed/USDA/FSIS/Tissue Residue
Landmark Center, Suite 300
1299 Farnam St.
Omaha, Nebraska 68102